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NICE's Social Value Judgements about Equity in Health and Health Care

CHE Research Paper 70

NICE's social value judgements about equity in health and health care

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Abstract

The National Institute for Health and Clinical Excellence (NICE) routinely publishes details of the evidence and reasoning underpinning its recommendations, including its social value judgements. To date, however, NICE's social value judgements relating to equity in the distribution of health and health care have been less specific and systematic than those relating to cost-effectiveness in the pursuit of improved sum total population health. NICE takes a pragmatic, case-based approach to developing its principles of social value judgement, drawing on the cumulative experience of its advisory bodies in making decisions that command respect among its broad range of stakeholders. This paper aims to describe the social value judgements about equity in health and health care that NICE has hitherto used to guide its decision making. To do this, we review both the general social value judgements reported in NICE guidance on methodology and the case-specific social value judgements reported in NICE guidance about particular health care technologies and public health interventions.

1. Introduction

The National Institute for Health and Clinical Excellence (NICE) routinely produces evidence-based guidance on health care technologies and public health interventions which influences National Health Service (NHS) and broader public sector resource allocation decisions in England and Wales. Among similar organisations elsewhere in the world, NICE is unusual in that it publishes details of the evidence and reasoning underpinning its decisions, including references to the social values that the Institute expects its advisory bodies to take into account when making recommendations (NICE, 2008a). NICE is arguably the first organisation in the world to do this systematically in routine resource allocation decisions, as opposed to selectively or in special 'one off' stakeholder consultation exercises, in the health sector or indeed any other sector of public policy making. NICE can thus be seen as a pioneering example of the 'accountability for reasonableness' framework for public resource allocation advocated by the bioethicist Norman Daniels, with its four requirements of: (i) publicly accessible decisions and the rationales for them, (ii) reasonableness of rationales in the sense both of giving reasons and applying relevant principles, (iii) the possibility of challenge through appeal and of revision of decisions, and (iv) the presence of mechanisms to ensure that the foregoing requirements are met (Daniels, 2000; Daniels and Sabin, 2008).

The values embodied in NICE decisions are ultimately those endorsed by its Board, but they have been informed by government policies, the experience of Board members, research (some initiated by NICE), the experience of members of advisory committees, reports of specific NICE workshops, public and other consultations, and the recommendations of the NICE Citizens' Council (NICE, 2008a). NICE's approach to social values is not driven by a single philosophical perspective (e.g. needs-based, duty-driven, utilitarian) but is pluralistic in that it draws on several traditions. It is also pragmatic, even casuistical¹, in that it operates through trying to take account of the particular circumstances of each individual case and the many parties having stakes in its procedures and decisions, it builds up cumulative records of individual cases to guide action, and it tries to ensure that the operational consequences of its decisions are manageable.

NICE has developed a clear and detailed set of principles for assessing 'cost-effectiveness', i.e. how to measure costs and health benefits and compare them in order to offer value for money ways of improving health. These include social value judgements about the appropriate construction and use of the quality adjusted life year (QALY) as a summary measure of health gain that can be compared between different individuals with different health conditions, the appropriate treatment of costs such as productivity costs and informal care costs falling outside NHS budgets, and the appropriate benchmark range of incremental cost-effectiveness ratios (ICERs) to be used for judging whether a decision option has an expected cost per QALY gained that can be considered cost-effective.

The general requirement is that recommended interventions of all kinds (including technologies, guidelines and programmes, in both health care and public health), have an ICER at or below the prevailing threshold range of values set by NICE. However, this is neither a necessary nor sufficient condition for an intervention to be recommended by NICE. The Institute Board has instructed its advisory bodies that cost-effectiveness should not be the sole basis for their decisions. Other factors also need to be taken into account. There will normally be a number of pragmatic considerations to be borne in mind, such as organisational impacts of the intervention's introduction and continued use, other policy objectives (such as supporting industrial innovation), and the overall size of impacts on population health and budgets. Furthermore, there are also a range of considerations relating to fairness in the distribution of health and health care between individuals, and the circumstances under which it is fair to place more weight on a QALY for one person rather than another. These are often grouped together as considerations of 'equity', as distinct from considerations of efficiency or cost-effectiveness in pursuing the objective of improved sum total population health.

Several potential equity considerations are described in official NICE documentation (NICE, 2008a). However, while the principles related to cost-effectiveness are relatively explicit, those covering equity concerns are generally less specific. Furthermore there is little guidance on how these equity

¹ Casuistry: case-based ethical reasoning (Jonsen and Toulmin, 1988). NICE adheres to ethical principles, which it tries to make as clear as possible, but also recognises that the circumstances of individual cases are often critical in determining the right thing to do. Cumulative records of individual cases over time are therefore also a source of guidance.

concerns should be balanced against concerns for cost-effectiveness. This paper aims to shed light on this important but underdeveloped subset of NICE's social value judgements (SVJs). It has two main aims:

1. To describe the substantive SVJs about equity in health and health care that NICE uses to guide its decision making.
2. To compare the general SVJs reported in NICE guidance on methodology with the case-specific SVJs reported in NICE guidance about particular health care technologies and public health interventions.

The paper starts with a background section, giving a brief overview of NICE, why it implemented a policy of making transparent SVJs, and why NICE's SVJs about cost-effectiveness are more specific than its SVJs about equity. It then proceeds to describe NICE's SVJs about three different types of equity concern. First, concern that health services should be distributed according to need. Second, concern that there should be no discrimination against health service recipients on the basis of their personal or social characteristics. Third, concern to reduce unfair health inequalities. In each case, we describe both general SVJs and case specific SVJs in separate sections. We then summarise and discuss our findings.

Our descriptions of existing NICE SVJs are based on a review of methodology guidance documentation and selected published items of guidance from the NICE Technology Appraisal Committee (TAC) about particular health care topics, and from the NICE Public Health Interventions Advisory Committee (PHIAC) about particular public health topics. The items of guidance were selected purposively to illustrate topics where NICE advisory bodies had to make difficult and unusual case-specific SVJs about equity without the benefit of pre-existing SVJ guidance of a detailed and prescriptive nature. This purposive selection was done on the basis of the authors' own experience², plus additional suggestions from two long serving TAC and PHIAC members with extensive experience across a broad range of topics. Full titles of the official items of guidance used as the basis of our descriptions of NICE's general SVJs, together with the shortened italicised titles that we use in the rest of the paper, are as follows:

1. Directions to NICE from the Secretary of State for Health (*SoS Directions*; NHS, 2005)
2. Social Value Judgements: Principles for the development of NICE guidance, 2nd edition (*SVJ Guidance*; NICE, 2008a)
3. Guide to the methods of technology appraisal, 2nd edition (*TA Guide*; NICE, 2008b)
4. Methods for the development of NICE public health guidance, 2nd edition (*PH Methods*; NICE, 2009a)
5. Appraising life-extending, end of life treatments (*EoL Guidance*; NICE, 2009b).

We also consulted relevant publications authored by senior NICE officials, but placed less emphasis on these on the basis that they represent personal or at most semi-official views about NICE SVJs rather than the official views of NICE ratified by the Institute Board.

² RC served as member of TAC from 2002-7 and PHIAC from 2007-9, AJC served as Vice Chair of NICE from 1999-2003 and Chair of NICE R&D Committee from 2007-10, and PL served as Clinical and Public Health Director of NICE from 1999-2011.

2. Background

NICE came into existence in 1999. In September of that year its chair, Sir Michael Rawlins, explained his priorities in the St Paul Healthcare Annual Lecture as follows: "I would emphasise ... that NICE is in many respects 'virtual' and will rely on the help and goodwill of colleagues in Royal Colleges, professional associations, the health service and universities throughout England and Wales ... perhaps most important of all, we need to earn and retain the confidence of patients and the public, health professionals and managers, and the health care industry." (NICE website, <http://www.nice.org.uk/aboutnice/whatwedo/corporatepublications/annualreports/Article.asp?a=336>, accessed 15 June 2011). A concern for transparency and explicit addressing of issues of value judgement, whether scientific or social, informed the procedures developed from the very beginning regarding NICE technology appraisals and, from 2005, public health interventions.

Transparency and openness of NICE procedures and its reasons for making particular recommendations were seen as critical for the credibility of NICE guidance. This included credibility to the clinical and managerial professions in the NHS, to patients and the organisations representing their interests, to the research community on whose evidence much was to depend, to the industries whose products NICE appraised, to the Secretary of State and Parliament and – by no means least important – to the general public and the media. These interest groups are commonly called 'stakeholders'. NICE needed stakeholder involvement because it was and still is, despite its enormous growth since 1999, largely a virtual organisation. Stakeholders are required to sit on its board as non-executive directors and to operate its advisory bodies, especially its three technology appraisal committees. Stakeholders also sit on NICE's clinical guideline development groups, which assess and make recommendations based on the evidence available on the guideline topic. Stakeholders are also needed to join and attend advisory groups, the patient involvement unit, and ad hoc groups (to develop technical advice on methods of appraisal, for example); and to observe processes and follow procedural guidance 'in the field'. For stakeholders, it is important for NICE to have authority in its scientific judgements (as assessed by scientists) and in its social value judgments (as assessed by other stakeholders); to be seen to be independent of industry, politicians, patient pressure groups, and special pleaders of all kinds; to be comprehensible to all stakeholders; and to demonstrate humanity by manifestly understanding the concerns of patients, families and caregivers, and the wider public. It is also important to be practical in the sense of issuing guidance that can be implemented, with clear and realistic timelines, effective communications (both in their process and in what they communicate), and a sense of do-ability at the workplace (Culyer, 2005).

NICE cares about the processes by which its conclusions are reached and its recommendations are made. It is, in particular, committed to what are sometimes described as 'deliberative processes' in developing its advice (Culyer and Lomas, 2006). A deliberative process requires the fullest identification of legitimate stakeholders (including the general public) in the decision making process and its consequences, the fullest practicable opportunities for them to comment on both the design of the process and the substantive discussions conducted within that process, and the fullest practicable participation in the decision making process itself. It further requires as much transparency as is consistent with managing an effective process that delivers good decisions in a timely fashion and that does not violate principles of privacy or confidentiality. A deliberative process is not only one in which the participants combine evidence of various sorts with values and other considerations; it is also a process through which new knowledge is revealed (for example from the experience, both personal and professional, of participants) and during which it is possible for people to change their minds in the light of new evidence and argument. The importance of deliberative processes becomes especially significant when the evidence base is unreliable and the social values at stake are ambiguous and contested, as may be the case more frequently in public health than elsewhere.

Initially, NICE found it difficult to address issues of equity with any degree of sophistication, other than in its procedures for publishing information and allowing stakeholders to comment and be consulted, which were well ahead of usual practice in such public decision making. The guidance in the first edition of its *Guide to the Methods of Technology Appraisal* (NICE, 2003) makes this very clear: "... an additional QALY is of equal value regardless of other characteristics of the individuals such as their socio-demographic details, or their pre- or post-treatment level of health. This position reflects the absence of consensus regarding whether these or other characteristics of individuals should result in differential weights being attached to QALYs gained" (para 5.9.7.2). Since 2003 NICE has put substantial effort into finding more effective means of addressing matters of equity. The Citizens'

Council was established to assess how the general public would address these issues through a deliberative process. The Council comprises thirty members of the general public who meet for three days to respond to specific questions posed by the Institute. The initial process was evaluated by the Open University (<http://www.hta.ac.uk/nihrmethodology/reports/1566.pdf>) and more recently the overall experience has been described by Littlejohns and Rawlins (2009).

In 2005, NICE and the Department of Health agreed to co-fund two research projects to investigate the social value of a QALY. Both of these projects were completed in 2008 and concluded that the public probably did want to weight QALYs but how to develop these weights remained uncertain (Dolan et al., 2008; Baker et al., 2010). The second edition of NICE's guide to the methods of technology appraisal states that: "The Institute considers equity in terms of how the effects of a health technology may deliver differential benefits across the population. Evidence relevant to equity considerations may also take a variety of forms and come from different sources. These may include general-population-generated utility weightings applied in health economic analyses, societal values elicited through social survey and other methods, research into technology uptake in population groups, evidence of differential treatment effects in population groups, and epidemiological evidence on risks or incidence of the condition in population groups." (*TA Guide*, p.18)

At the time of writing, the UK coalition government that came to power in 2010 is consulting on proposals to reform the way NICE operates and in particular to introduce a new system of 'value based pricing' for branded medicines (Department of Health, 2010). This proposed new system will mean that, at least in the case of branded medicines, NICE will provide the evidence base for price negotiations. The proposals also include potentially important changes to NICE social value judgements about equity – for example, they suggest giving more weight to QALYs accruing to patients with relatively severe illnesses which impose a relatively high burden of disease (Department of Health, 2010). However, we do not review these proposals in this paper since they have not been finalised and do not reflect official NICE guidance on SVJs at the time of writing. The SVJ issues we discuss in this paper are likely to remain highly relevant to NICE's operations in the future environment of value based pricing, and in any case are of continuing international interest given NICE's pioneering role in this arena.

3. Equity concern for distributing health services according to need

3.1 General SVJs – as reported in general NICE guidance

The Secretary of State's Directions to NICE require that its evaluations of health care interventions should take into account, amongst other things, "the degree of clinical need of patients with the condition or disease under consideration" (*SoS Directions*). Rawlins et al. (2010) describe severity of illness as one of the 'special circumstances' to which NICE's advisory bodies have given 'special weighting', reflecting evidence that many people value the health gains accruing to severely ill individuals more highly than equal-sized health gains accruing to those whose illness is relatively mild (Shah, 2009).

In January 2009, NICE issued supplementary advice to its Technology Appraisal Committees (TACs) to be taken into account when appraising life-extending end of life treatments (*EoL Guidance*). This indicated that, if certain criteria are met, it may be appropriate to recommend the use of such treatments even if their ICERs exceed the upper end of the range normally considered acceptable. The TACs are instructed to consider the impact of giving greater weight to the health gains achieved in the later stages of disease, by assuming that the extended survival period is experienced at the full quality of life anticipated for a healthy individual of the same age. They are also instructed to consider the magnitude of additional weight that would need to be assigned to the health gains in order for the ICER to fall to an acceptable level. This has been argued to reflect the special value society places on prolonging the lives of terminally ill patients (Rawlins et al., 2010). Some aspects of the supplementary advice were revised following a five week public consultation exercise. The criteria that need to be satisfied in order for the advice to be applied are currently as follows (*EoL Guidance*):

- "The treatment is indicated for patients with a short life expectancy, normally less than 24 months;
- There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional three months, compared to current NHS treatment;
- The treatment is licensed or otherwise indicated, for small patient populations."

The NICE SVJ guidance does not say anything about whether the unavailability of alternative effective treatments might affect the acceptability of a given technology's cost-effectiveness. The supplementary advice regarding end of life treatments proposed initially included, in addition to the above, the following criterion:

- "No alternative treatment with comparable benefits is available through the NHS."

This criterion was used in the end of life test cases. For example, in the appraisal of sunitinib for renal cell carcinoma, the Committee noted that the technology provided a 'step change' in the first-line treatment options for advanced and/or metastatic disease (NICE, 2009c). Eventually, however, the criterion was dropped from the supplementary advice following the public consultation. Among other things, comments made during the consultation exercise included pragmatic concerns about what types of treatment could be considered as an 'alternative' (for example, any treatment theoretically available, or only those that have been approved by NICE, or only those that are used routinely).

Finally, NICE SVJ guidance explicitly addresses the issue known in the literature as the 'rule of rescue' or the 'identifiable victim effect' (McKie and Richardson, 2003; Cookson et al., 2008). The second edition of the SVJ guidance document states: "There is a powerful human impulse, known as the 'rule of rescue', to attempt to help an identifiable person whose life is in danger, no matter how much it costs ... NICE recognises that when it is making its decisions it should consider the needs of present and future patients of the NHS who are anonymous and who do not necessarily have people to argue their case on their behalf. NICE considers that the principles provided in this document are appropriate to resolve the tension between the needs of an individual patient and the needs of present and future users of the NHS. The Institute has not therefore adopted an additional 'rule of rescue'." (*SVJ Guidance*, pp.20-21). This guidance on 'rule of rescue' was issued in 2008, following deliberation and consultation about this specific issue including a Citizens' Council meeting in 2006, and predates the supplementary guidance on life-extending end of life treatments issued in 2009. However, as the SVJ guidance makes clear, NICE sees these as separate issues and does not seek

to favour identifiable patients who need an intervention being appraised by NICE over anonymous patients who need other forms of care.

3.2 Case-Specific SVJs – as reported in NICE guidance on health care technologies and public health interventions

As noted above, since early 2009 NICE has instructed its advisory bodies to consider giving special weighting to the health gains offered by life-extending treatments for individuals in the later stages of terminal illness. However, there are cases of NICE giving special consideration to such treatments that pre-date this supplementary guidance. For example, in the appraisal of riluzole for motor neurone disease, the TAC considered the “severity and relatively short lifespan” of affected patients, and recommended the use of this technology despite the fact that the ICER estimates ranged between £34,000 and £43,500 per QALY gained (NICE, 2001). Similarly, trastuzumab combination therapy was recommended for use in the treatment of advanced breast cancer even though the manufacturer provided an ICER estimate of £37,500 per QALY gained. This was due in part to the TAC’s observation that “improvements in survival of this magnitude due to therapeutic intervention have rarely been recorded in women with metastatic breast cancer” (NICE, 2002).

Between January 2009 (when the supplementary guidance was issued) and April 2009, nine technologies were considered by NICE in the context of the end of life criteria, because they were associated with a life expectancy of less than 24 months and the estimated ICERs exceeded the range normally considered acceptable (Longson and Littejohns, 2009). All nine related to treatments for cancer. Three of these technologies were considered not to fulfil all of the criteria – bevacizumab for renal cell carcinoma because it was licensed for other indications that have large eligible patient populations; lapatinib for breast cancer and cetuximab for head and neck cancer because the available evidence suggested that neither offered a life extension of at least three months. For the remaining six technologies, it was assumed that the extended survival period would be experienced at the full quality of life anticipated for a healthy individual of the same age, in accordance with the supplementary guidance. In addition, the TAC also considered the magnitude of implicit weightings that would need to be assigned to the health benefits offered by the technologies in order for the ICERs to fall within the normal threshold range. For example, in the case of sunitinib for renal cell carcinoma, it was noted that the health gains would need to be valued 70 percent higher than those achieved in other circumstances for the ICER to fall to £30,000 per QALY gained. Three of the six technologies were eventually recommended as treatment options: sunitinib for the first-line treatment of renal cell carcinoma (most plausible ICER without end of life weighting: approximately £50,000 per QALY gained), lenalidomide for multiple myeloma (more than £43,800 per QALY gained), and sunitinib for gastrointestinal stromal tumours (£31,800 per QALY gained).

We did not identify any clear-cut examples of TACs giving explicit additional weight to QALY gains from treatments for severe but non-terminal illnesses. However, there are cases where TACs have taken severity of illness into account in a rather different way: by making a special effort to identify a small sub-group of severely ill patients for whom the technology might be considered cost-effective. In the appraisal of omalizumab for severe persistent allergic asthma, for instance, the Committee was persuaded that the technology could be considered cost-effective for a small sub-group of severely ill patients, even though the ICER estimates for the broader patient group exceeded the range normally deemed acceptable (NICE, 2007). The guidance document explained this decision as follows: “Overall, therefore, the Committee concluded that there were a number of considerations which meant the ICER was higher than acceptable for patients with severe persistent allergic asthma. However, the Committee was persuaded that for a narrowly defined severely affected group of asthma patients, at an elevated risk of asthma-related mortality, cost-effective treatment with omalizumab was possible, if therapy was discontinued in non-responders at 16 weeks and if vial wastage could be minimised to reduce costs” (NICE, 2007).

4. Equity concern for non-discrimination

4.1. General SVJs

NICE must comply with legislation on human rights, discrimination and equality, at both the scoping and appraisal stage (*TA Guide*, p.10). In particular, the 2010 Equality Act specifies nine 'protected characteristics' which cannot be used as a reason to treat people unfairly: age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief; sex, and sexual orientation. The current version of the UK public sector equality duty, which came into force on 5 April 2011, states that public bodies must have due regard to the need to: eliminate unlawful discrimination; advance equality of opportunity between people who share a protected characteristic and people who do not share it; and foster good relations between people who share a protected characteristic and people who do not share it (<http://www.homeoffice.gov.uk/equalities/equality-act/equality-duty/>, accessed 22 September 2011).

As well as these nine "protected characteristics", NICE's concern for non-discrimination extends to three further characteristics: conditions associated with stigma, behaviour-dependent conditions, and socio-economic status (*SVJ Guidance*, pp.23-25). NICE ensures that "patients are not denied access, or have different or restricted access, to NHS care because of their race, disability, age, sex/gender, sexual orientation, religion, beliefs, or socioeconomic or other status" (*SVJ Guidance*, p.23).

NICE seeks to treat the same those who are the same in a relevant respect – a horizontal equity objective (Culyer, 1995). The Institute's general principle is that ethnicity, age, gender, sexuality and other social characteristics should not affect decisions about whether to recommend a given intervention. However, these characteristics may be taken into account if there is clear evidence that they are indicators for the risks or clinical effectiveness of that intervention (*SVJ Guidance*). More specifically, principle 7 of the NICE SVJ guidance states that: "NICE can recommend that use of an intervention is restricted to a particular group of people within the population (for example, people under or over a certain age, or women only), but only in certain circumstances. There must be clear evidence about the increased effectiveness of the intervention in this subgroup, or other reasons relating to fairness for society as a whole, or a legal requirement to act in this way" (*SVJ Guidance*, p.25).

NICE also seeks to treat differently those with different needs – a vertical equity objective (Culyer, 1995). For example, it "should take special account of the needs of disabled people, which includes whether there are obstacles that might prevent them from benefitting from NICE guidance" (*SVJ Guidance*, p.23). However, similar considerations have not been explicitly applied to other characteristics that may be indicative of obstacles to benefitting from NICE guidance (such as socioeconomic status or religious beliefs).

NICE explicitly does not discriminate according to the cause of illness or how 'deserving' of treatment an individual may be. In particular, "NICE should not produce guidance that results in care being denied to patients with conditions that are, or may have been, dependent on their behaviour" (*SVJ Guidance*, p.25). This would include conditions that may have been contracted or exacerbated due to the individual's lifestyle or occupation. In line with principle 7, however, "if the behaviour is likely to continue and can make a treatment less clinically effective or cost-effective, then it may be appropriate to take this into account" (*SVJ Guidance*, p.25). In part, this reflects the general principle that the NHS ought to distribute health care according to need, rather than desert. However, NICE's position also reflects the fact that it is "often impossible, in an individual, to decide whether the condition was dependent on their own behaviour or not" (*SVJ Guidance*, p.24). Further, taking into account the cause of illness may entail discrimination on grounds of gender (for example, where a behavioural health risk is associated with male-dominated occupations) or socioeconomic status (for example, where a behavioural health risk is more prevalent amongst low income individuals).

NICE also advises that it should evaluate 'orphan drugs' (treatments for rare conditions) "in the same way as any other treatment" (*SVJ Guidance*, p.20). It also considers that the standard approach to assessing cost-effectiveness is appropriate for the evaluation of conditions associated with stigma (for example, sexually transmitted diseases), although it expects its advisory bodies to consider the possibility that "stigma may affect people's behaviours in a way that changes the effectiveness of an intervention" (*SVJ Guidance*, p.24).

4.2 Case-Specific SVJs

There is rarely any explicit discussion of non-discrimination principles in the 'considerations' section of NICE appraisals. This is because non-discrimination principles are used mainly to rule out of consideration any decision options which might discriminate against certain patient groups, rather than to weigh up the pros and cons of the decision options that are actively considered. However, we describe below a test case, involving an appeal in which NICE was accused of violating non-discrimination principles by favouring a technology predominantly used to treat a form of cancer linked to male occupational exposure to asbestos during the 1970s. The appeal was submitted by a Primary Care Trust, doubtless concerned about the financial implications of the recommendation. The appeal was rejected, on the grounds that the technology was cost-effective and the TAC had not given any special priority to this patient group on the grounds of occupational exposure. This is a potentially important test case, as it suggests that non-discrimination principles do not just apply to 'within-treatment' decisions about restricting the use of the same treatment to one patient sub-group rather than another, but may also apply more generally to 'between-treatment' decisions about whether to recommend use of one treatment for one condition rather than a different treatment for a different condition.

Malignant pleural mesothelioma (MPM) is a type of cancer that occurs in the pleura, the membranous lining surrounding the lungs. Presentation and diagnosis often occur at an advanced stage, at which point the prognosis for most patients is extremely poor (median survival is nine to 13 months). Approximately 90 percent of cases of MPM are linked to asbestos exposure. A wide range of occupations, notably those in the shipbuilding, railway engineering and asbestos product manufacture industries, are associated with an increased risk of MPM. A peak incidence of MPM is expected in men in the 1948 to 1953 birth cohort due to the high utilisation of asbestos in the 1970s. Family members of people whose work clothes were contaminated with asbestos fibres have also developed MPM. The use of asbestos was banned in the UK in 1999.

In 2008, NICE evaluated the use of pemetrexed with cisplatin for the treatment of MPM (NICE, 2008). The results of the pivotal trial showed that this combination treatment confers a survival benefit of approximately three months compared with cisplatin alone, as well as offering advantages in terms of time to disease progression, tumour response rate and quality of life. The Assessment Group estimated an ICER of £34,500 per QALY gained for the patient subgroup comprising the majority of MPM patients seen in UK clinical practice, which was higher than the range normally considered acceptable.

The TAC considered that the economic analyses may have underestimated the overall quality of life benefits offered by pemetrexed combination therapy, whilst potentially overestimating the costs of the treatment in UK clinical practice. It also noted that MPM is "a rare and aggressive malignancy caused by occupational exposure to asbestos" and that it has a "very poor prognosis". Considering these factors together with the available clinical and cost-effectiveness evidence, the TAC agreed that the ICER was likely to fall within acceptable levels, and therefore recommended the use of pemetrexed in combination with cisplatin as a treatment option for MPM for the defined subgroup.

However, Birmingham East and North Primary Care Trust (PCT) submitted an appeal against this decision, alleging that the TAC had failed to take account of the principles of NICE's own SVJ guidance and that the final recommendations were perverse in light of the evidence submitted. The PCT alleged, *inter alia*, that the TAC appeared to have taken into account the fact that MPM is typically contracted via occupational exposure. This, in the view of the PCT, was an irrelevant consideration. The PCT argued that, in reaching decisions about treatment, NICE should assess patients as they present and irrespective of the circumstances which led to them contracting the condition. By taking into account occupational exposure, it risked discriminating against patient groups and/or on gender grounds.

In response to this point, the Appeal Panel heard that when reaching its conclusion the TAC had taken into account those matters relating to the likelihood of greater quality of life benefits and lower costs than assumed by the cost-effectiveness analyses. Matters relating to the cause of the disease had been noted by the TAC but were not actually factors in its recommendation. The Appeal Panel accepted these reassurances and dismissed the appeal on this point.

5. Equity concern for reducing unfair health inequalities

5.1 General SVJs

NICE distinguishes two approaches to allocating health care resources: the 'utilitarian approach' and the 'egalitarian approach'. More specifically, "the utilitarian approach involves allocating resources to maximise the health of the community as a whole" whereas "the egalitarian approach involves distributing healthcare resources to allow each individual to have a fair share of the opportunities available" (*SVJ Guidance*, p. 9). The *Guide to the Methods of Technology Appraisal* defines a reference case assumption that all equal-sized health improvements "should receive the same weight regardless of any other characteristics of the people receiving the health benefit" (*TA Guide*, p.49) (often referred to as the 'a QALY is a QALY is a QALY' rule). However, the Institute recognises that this simple approach – which accords with the utilitarian approach as defined above – may, in some circumstances, not be appropriate: treating QALYs equally is not necessarily the same thing as treating individuals fairly.

One important dimension of the egalitarian approach defined above is concern to reduce health inequalities. This is importantly different from concern to distribute health care according to need, as the focus is on health rather than health care. Equal health care is not the same thing as equal health, as health care is only one among many important determinants of health.

In general, and in accordance with the relevant equality legislation, NICE seeks to identify opportunities for promoting equality in all forms of guidance (*SVJ Guidance*, p.12; *PH Methods*, p.10) and expects its advisory bodies to ensure that implementing NICE guidance will not widen existing inequalities (*SVJ Guidance*, p.28). Arguably, however, use of the term 'inequalities' in this context refers to non-discrimination principles and social inequalities in general rather than health inequalities in particular.

Specific concern for health inequality reduction is largely confined to NICE documentation relating to public health. The *Methods for the development of NICE public health guidance* document emphasises NICE's concern to reduce health inequalities, whereas the *Guide to the methods of technology appraisal* makes little mention of this issue. This suggests that health inequality reduction principles have been considered to be more relevant to public health rather than health care decisions. However, this is an implicit distinction; there is no explicit ruling that health inequality reduction is less relevant to health care decisions. It may also be the case that in a health care context it is harder to navigate tensions between equity principles relating to health inequality reduction and equity principles of non-discrimination. This tension is clearly brought out in the SVJ guidance document. Principle 8 of the *Social value judgements: principles for the development of NICE guidance* document states: "When choosing guidance topics, developing guidance and supporting those who put its guidance into practice, the Institute should actively consider reducing health inequalities including those associated with sex, age, race, disability and socioeconomic status." However, it goes on to state: "NICE should not recommend interventions on the basis of individuals' income, social class or position in life. Nor should individuals' social roles at different ages affect decisions about cost-effectiveness" (*SVJ Guidance*, p.25).

NICE distinguishes between inequity and inequality: "health inequity is concerned with social justice, value or politics, while inequalities in health are a matter of fact" (NICE glossary, <http://www.nice.org.uk/website/glossary/>, accessed 5 August 2011). However, NICE offers little specific guidance about the criteria for assessing how far particular health inequalities are unjust or unfair or inequitable, or how concern for reducing unfair health inequality is to be balanced against concern for improving population health.

One specific recommendation is that, although special efforts need to be made to improve the health of the most socially disadvantaged groups, efforts should "focus on all levels of the [health and socioeconomic] gradient" (*PH Methods*, p.12).

A second specific recommendation is that it may sometimes be justified to recommend interventions which improve population health but slightly widen health inequalities. For instance, *Methods for the development of NICE public health guidance* states that, ideally, a health intervention should "benefit health in all groups, while reducing health inequities. However this intention may in practice be difficult

to achieve. It may be justified in certain circumstances to increase overall population health while relative differences between groups remain the same (or get slightly worse)" (*PH Methods*, p.11). This excerpt indicates that the utilitarian approach may be followed at the expense of increasing health inequalities in some situations, as the overall increase in health may compensate for the deterioration in the distribution. This is important because public health interventions that produce overall health improvement often exacerbate relative health differences between the most and least advantaged groups in society (*PH Methods*, p.12). For example, policies aimed at reducing hazards in 'white collar' workplace environments will not benefit those who are unemployed or who work in (traditionally lower pay) manual occupations. Thus, there may be a trade-off between achieving overall health improvement and reducing health inequities (Graham and Kelly, 2004). *Methods for the development of NICE public health guidance* states that decisions need to be made on a case-by-case basis, and that it may be appropriate to apply hybrid actions which contain elements of both universal approaches designed to produce overall population health improvement and a targeted focus on the most disadvantaged (*PH Methods*, p.142).

Finally, NICE's adherence to the principle of non-maleficence (*SVJ Guidance*, pp.8-9) suggests that it is not permissible to recommend an intervention that may reduce the health of advantaged individuals, even though this may reduce health inequality. For example, no-one would seriously recommend a policy of free vouchers for cigars and fast food for well-to-do individuals and communities, however effective this might be in 'levelling down' socio-economic inequalities in health.

5.2 Case-Specific SVJs

We did not identify any cases to date in which NICE has explicitly departed from the 'a QALY is a QALY is a QALY' principle in order to pursue health inequality reduction objectives. It has, however, 'taken into account' health inequality reduction objectives. Furthermore, as explained below, NICE has *implicitly* departed from this principle by recommending targeted rather than universal versions of an intervention.

It is often the case that public health programmes tend to benefit individuals who are already quite healthy, and therefore result in increased health inequalities. This is true of smoking cessation services, for example, which in the past have been found to be least likely to attract people from sectors of the population where smoking rates are high. Hence, when asked to evaluate workplace-based smoking cessation interventions, PHIA considered not only the available evidence on the effectiveness and cost-effectiveness of the options, but also the fact that the workplace setting offered a means of targeting groups that traditionally have been difficult to reach (such as young men), and could help therefore to reduce health inequalities (NICE, 2007). However, the cost per QALY gained estimate was well within NICE's normal threshold range anyway, so the intervention could be recommended as cost-effective without recourse to giving additional weight to health gains for hard-to-reach groups.

It is a common feature of PHIA decision making that the relevant cost per QALY gained estimates are well within NICE's normal threshold range. Health inequality reduction concerns can therefore be addressed without needing explicitly to depart from the 'a QALY is a QALY is a QALY' principle. In some cases, however, there may be an *implicit* departure from this principle when PHIA recommends an intervention targeting disadvantaged populations. This is because it may be possible to find a universal form of the same intervention with an even lower cost per QALY gained. Even if the targeted intervention has a cost per QALY gained below the £20,000 to £30,000 range normally considered acceptable and is therefore cost-effective compared with ordinary displaced programmes in the NHS, it may not be cost-effective compared with the universal intervention. Hence it might in principle be possible to increase population health by approving the universal intervention rather than the targeted intervention. The decision to spend money on the targeted intervention is then an *implicit* decision to depart from 'a QALY is a QALY is a QALY' and to give greater weight to the health gains for the disadvantaged population. In such cases, PHIA itself typically does not explicitly seek to calculate whether a more universal variant of an inequality-reducing intervention might be more cost-effective, so any potential departure remains implicit.

6. Discussion

Our central finding is that, although NICE advisory bodies are authorised to depart from the social value judgement that 'a QALY is a QALY is a QALY' on grounds of equity, they have in practice been extremely reluctant to do so explicitly except in the special case of life-extending end of life treatments. However, advisory bodies have taken into account a range of equity considerations in more implicit ways, without explicitly setting additional weight on QALY gains arising in particular circumstances to individuals with particular characteristics. We can identify three main examples.

First, all advisory bodies follow non-discrimination principles which rule out from consideration any decision options that would fall foul of anti-discrimination legislation. This may have an implicit health opportunity cost, insofar as some discriminatory options might conceivably be highly cost-effective. However, this does not imply that NICE gives additional weight to QALY gains for some patients rather than others: rather, it implies that NICE sees non-discrimination as an important ethical constraint on the objective of health maximisation.

Second, TACs take into account concern for severity of illness and sometimes make special efforts to identify special restrictions on the use of a technology that might allow it to be considered cost-effective for a severely ill sub-group of patients. This does not explicitly involve special additional weight to QALY gains for severely ill patients, since NICE recommends the technology only if these special restrictions result in a cost per QALY gained within the range normally considered acceptable.

Third, PHIA takes into account concern for reducing unfair health inequalities and sometimes recommends targeted delivery of health prevention services towards more socially disadvantaged individuals or communities. This has not involved explicitly setting special additional weight on QALY gains for disadvantaged populations, however, since the reported cost per QALY gain is typically well below the range normally considered acceptable. Rather, concern for unfair health inequality is taken into account in the prior selection of interventions and decision options for consideration. Arguably, however, the decision not to consider other more universal forms of delivery that might be even more cost-effective ways of improving population health represents a form of *implicit* additional weight on QALY gains for disadvantaged populations and to have settled the matter at a higher level of decision making lifts a burden from PHIA that it may not feel able to bear.

It remains to be seen whether NICE's advisory bodies will in the future take decisions which explicitly imply a special additional weight on QALY gains to severely ill populations, or to socioeconomically disadvantaged populations, or to children, or to some other population sub-group that might reasonably be argued to have a special additional claim to health resources on equity grounds. The reluctance of advisory bodies to do so without specific instruction from the Institute Board is understandable, given the complex and politically controversial nature of equity concerns. An explicit decision that departs from current practice by giving explicit additional weight to QALY gains for a particular population group carries substantial risks of intense media attention, protracted legal appeals, and the setting of unhelpful precedents. The risks in giving special additional weight to QALY gains for socio-economically disadvantaged populations are obvious, as this carries the logical but highly controversial implication that lower weight should be given to QALY gains for socio-economically advantaged populations. There are also less obvious but nonetheless important risks attached to giving special additional weight to QALY gains for severely ill patients, as this carries the logical implication that lower weight should be given to QALY gains for less severely ill populations. One potentially uncomfortable implication is that lower weight should be given to QALY gains arising from preventive public health interventions targeting relatively healthy populations. Another potentially uncomfortable implication arises from the fact that spending on patients in their last year of life is almost five times as much as for others (Hoover et al., 2002). The principal bearers of opportunity costs within the NHS may therefore not be 'average' members of the community but relatively sick and elderly people to whom a significant priority ought perhaps to be attached on account of their severity of illness. Special priority to QALY gains for severely ill patients might therefore imply a higher valuation of the health opportunity costs from programmes displaced by NICE-recommended technologies, resulting in a less generous threshold range of ICERs and a more stringent cost-effectiveness test for technologies appraised by NICE.

It may of course be possible to avoid potentially uncomfortable implications of this kind by developing a nuanced and context-sensitive set of general QALY weighting principles. However, advisory bodies

are not in a good position to do this, as they are charged with making the particular decision in front of them and are not able to think through the logical implications for the full range of NICE's decision making. On the other hand, the Institute Board is naturally reluctant to impose prescriptive new guidance on advisory bodies that departs substantially from current practice. As already noted in the background section, NICE needs to build and maintain the confidence of a broad range of stakeholders with divergent views. For this reason, the Institute Board has always preferred a pragmatic incremental approach in which social value judgements are developed in an iterative process through cumulative case-based experience and only later (if at all) codified into general principles.

Despite this careful, somewhat tentative, approach to social value judgments, the fact that NICE has explicitly identified so many of the issues and opened them up for research and public discussion must be counted as remarkable pioneering achievements not to be found elsewhere in decision making, in the UK or anywhere else, about public investments. It is surely an experience from which similar agencies elsewhere might usefully learn.

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